

RE: CSMP SOP - Latest revision 07-02-10

From:

"Gustin, Dave" <dave.gustin@mckesson.com>

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Date:

Mon, 26 Jul 2010 17:03:47 +0000

Team,

There is an important aspect to this that had been over-looked and that is to always restore the customer's buffer when we put the TCR in. If service first passes along that the customer want 3000 more doses of something we need to realize that there is a good chance they are asking for what they think they need. Not what they need plus 10% rounded up. So please remember to adjust their request by 10% rounded up before filling out the SharePoint TCR and include in your comments that the buffer has been added. I.E. the customer thinks they will need 11,000 doses of Oxy. The TCR request would then be for 11,000 plus 1100 rounded up to the next highest thousands mark or in this case 13,000. That will help us tremendously to avoid repeated omits in the future and lighten the workload in term of calls and reports and etc, not to mention reduce the nuisance factor for our customers. Thx

Dave Gustin DRA North Central

937 840 8553

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From: Gustin, Dave

Sent: Monday, July 26, 2010 10:40 AM

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Cc: Jonas, Tracy; Hilliard, Gary; de Gutierrez-Mahoney, Bill; Oriente, Michael; McDonald, Tom

Subject: FW: CSMP SOP - Latest revision 07-02-10

NC team, now that everyone in the region is on the Service First program for Threshold Warning Report (TWR) first response calls I thought I would share with you a finalized version of their internal SOP (attached) covering what they do and how they do it. It is, in my opinion, working very well, has provided substance and documentation to the process and at the same time freed the ops and sales folks up from doing this very essential but time consuming function. Please let me know of any questions you have after you have read the attached and not found your answers there. Thanks

Below you will see the updated version of TCRs and what happens as well as whom does what when in the accts have asked for an increase.

Please remember that all Omits on the OMIT V reports are still followed up on the same way they always have been per the SOP in MOM. Only the TWR that I email out is under the Service First realm of responsibility. Thx

1.3 Threshold Change Requests

Existing customers may request a re-evaluation or increase to their existing controlled substances threshold due to business requirements and/or an emergency situation. All requests for a threshold change must be documented on the "Threshold Change Request" form located at the Regulatory SharePoint website <http://collaborate.mckesson.com/SiteDirectory/WMS/RegAffairs/default.aspx> as directed below.

NOTE: All requests for normal threshold changes need to be completed by a McKesson account manager and /or McKesson DC management. Emergency threshold requests may be initiated through the DC management.

1.3.1 Ordinary Threshold Change Request

The decision process time frame will vary depending on the nature of the request, availability of documentation and previous due diligence.

How to do:

- All threshold change requests must be submitted via the Regulatory Affairs SharePoint website (<http://collaborate.mckesson.com/SiteDirectory/WMS/RegAffairs/default.aspx>), reviewed and approved by the Operations Management Team of the Distribution Center servicing the account, and the customer's associated home office or regulatory department. Threshold change requests (TCRs) should be the Director of Regulatory Affairs responsible for the Region. A template for recording these requests electronically has been created. The directions are listed below. NOTE: Level I investigations and TCRs can be performed using the same template. The steps below detail the all areas of the form. The requests can be made by anyone authorized by the DO/DCM to do so. RNA managers are likewise authorized through RNA management.
- A. Access the SharePoint Regulatory Affairs website and, from 'Lists' in the left margin, select Add Customer TCR and Other Documents Here'.
 - B. From the header, select 'New'.
 - C. Complete all required fields identified by the red asterisk next to the heading.
 1. Name the document. Generally this is accomplished by listing the customer name and document type. For example, Mahoney's Pharmacy TCR. Note: 'Title' does not refer to the official title of the submitter. It refers to the document and will be used as a reference tool for research.
 2. Enter your name in the 'Submitter Name' field.
 3. From the drop down menu, select the servicing distribution center. RNA account managers will select the specific Retail National Account.
 4. Enter the customer name.
 5. Customer contact, title and phone number are optional.
 6. Enter the customer's DEA number.
 7. Enter the Customer's account number.
 8. From the drop down menu, select the document type (TCR in this case).
 9. Enter the supporting information relative to the change being requested. Be specific with your language.
 - D. Although the following information fields are not identified with an asterisk, they are required for TCRs.
 1. From the drop down menu, select TCR type (permanent or temporary).
 2. From the drop down menu, select the reason for the TCR.
 3. From the drop down menu, select the base ingredient.
 4. From the drop down menu, select the action.
 5. From the drop down menu, select the amount.
 6. When complete, select 'OK' at the bottom of the template.
 - E. The template can be used for multiple basecode changes.
 - F. RNA accounts where customers are completing the old style forms will post documents as follows:
 1. Follow all steps listed in number 2. above.
 2. From the header on the template form, select attach file
 3. Attach the old form TCR from the customer.
 4. When complete, select 'OK' at the bottom of the template.
 - G. Correctly executed TCRs will generate automatic email notifications to the submitter and the approver.
 1. Approves will view the document through the link to make sure they are complete and accurate.
 2. They will then approve the document by selecting 'Edit' within the email body.
 - a. The fast path will take the approver to the Regulatory SharePoint approval screen.
 - b. Select 'Edit' from the header.
 - c. Select either 'approved' or 'denied' from the drop down menu.
 - d. Comments are optional
 - e. Select 'Complete' at the bottom of the template.
 - H. A validation email is automatically generated by SharePoint to the submitter and the approvers informing all that the document is complete and approved.
 - I. SharePoint automatically files the document in the "Historical TCR and Customer Documents" page accessible from the 'Lists' menu on the Regulatory SharePoint site.

Refer all questions to your Regional Director of Regulatory Affairs.

1.3.2 Emergency Threshold Change Request.

The decision process time for an emergency request shall be 2 hours from the point of customer contact

How to do:

- A. The decision of whether a request is truly an emergency lies with the DC management.
 1. Once DC management has determined that a request is an emergency, the DC management will collect all the pertinent information regarding the request on the Threshold Change Request form located at the SharePoint Regulatory site. If the DC management approves the request, they will contact their DRA (24/7) via the contact call chain described here: (phone numbers previously communicated)
 - a. Contact your region's DRA (office/cell/home). If not available
 - b. Contact Gary Hilliard (office/cell/home). If not available
 - c. Contact any other DRA (office/cell/home)
 2. If the DRA concurs with the DC management's assessment, they will update the customers' thresholds immediately.
 3. DC management will notify the customer immediately upon approval of the threshold change.
 4. If DC management and/or DRA rejects request, customer is to be notified immediately by DC management of denial.
 5. All results (denial or acceptance) are to be documented on threshold change form and retained by DC management (with copy to DRA) in CSMP file.

Dave Gustin DRA North Central

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From: Melvin, Jennifer
Sent: Monday, July 26, 2010 10:18 AM
To: Gustin, Dave
Cc: Mooney, Scott; Dominguez, Jeni
Subject: CSMP SOP - Latest revision 07-02-10

Dave,

This is the most recent version of the CSMP SOP for ServiceFirst. Forward your additions for sharepoint & we will add them to the SOP.

Thank you,

Jennifer Melvin

ISMC Supervisor

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